

## REMARKS

Claims 6-14 and 21-32 are pending in this Application, with claims 6, 9 and 24 being independent claims. Claims 6-14 have been amended herein. Claims 15-20 have been cancelled. Claims 21-32 are new. No new matter has been added by these amendments.

The Examiner requested that the Applicants provide more details in the Abstract. Claims 6-20 stand rejected under 35 U.S.C. § 101. Claims 6-12 and 15-20 stand rejected under 35 U.S.C. § 102(b). Claims 6-13 and 15-20 stand rejected under 35 U.S.C. § 103. These rejections are traversed for the reasons below.

### The Abstract

The Examiner requested that the Applicants provide more details in the Abstract. The Abstract has been amended to include more details as requested by the Examiner. Thus, the Applicants request that any objection to the Abstract be withdrawn.

### The Claims include Eligible Subject Matter

Claims 6-20 stand rejected under 35 U.S.C. § 101 for claiming an unpatentable body part. This rejection is traversed for the reasons below.

35 U.S.C. § 101 sets forth the categories of eligible subject matter including, for example, any machine, manufacture or composition of matter. As long as the subject matter of an invention comes within one or more of these categories, the subject matter is eligible for patenting. See M.P.E.P. 706.03(a). For example, “manufacture” has been defined to mean “the production of articles for use from raw materials prepared by giving to these materials new forms, qualities, properties, or combinations whether by hand labor or by machinery.” M.P.E.P. 2105 (emphasis added) (quoting the U.S. Supreme Court in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)).

Here, independent claims 6 and 9 as amended fit squarely within the “machine” or “manufacture” categories of Section 101. Independent claims 6 and 9 include recitations of a reconstructed vertebral body comprising a region of cancellous bone that has been compressed, another region of substantially uncompressed cancellous bone, a first region of bone filler

material and a second region of bone filler material. Similarly, new independent claim 24 includes recitations of a reconstructed vertebral body comprising a region of cortical bone, a region of cancellous bone that has been compressed, another region of substantially uncompressed cancellous bone, a first region of bone filler material and a second region of bone filler material. In sum, these claim recitations include a combination of different components: body tissues (e.g., cancellous bone) and other components (e.g., a bone filling material). These claims satisfy at least the definition of a “manufacture:” the claims recite raw materials that, at least in some embodiments, are prepared by hand labor to give the materials new forms, qualities, properties and/or combinations. Thus, such claims fit squarely within at least the “manufacture” category of Section 101.

Moreover, the U.S. Patent Office has previously issued such claims having recitations to body tissue because such claims fit within an eligible category of Section 101. For example, the Applicants note recently-issued U.S. Patent 6,979,352, which includes several claims directed to the combination of components, some of which are body tissues (see, e.g., claims 15-31). For example, claim 15 recites “[a] structure prepared from a native fractured vertebral body having a porous cancellous bone . . . , comprising: a) a skeleton portion disposed within the porous cancellous bone structure of the fractured vertebral body; and b) a bone paste interdigitated within at least a portion of the skeleton portion.” As this example illustrates, a claim including recitations of body tissue and other components fits within an eligible category of Section 101.

Furthermore, the Applicants direct the Examiner’s attention to a co-pending patent application Serial No. 10/458,235, which is being examined by Examiner Julian Woo in Art Unit 3731. In this co-pending patent application, a similar rejection under 35 U.S.C. § 101 was also included in an Office Action mailed on January 3, 2006 and overcome by the response filed on June 30, 2006.<sup>1</sup>

Thus, the claims are directed to subject matter eligible for patenting and the Applicants respectfully request that the outstanding rejection under 35 U.S.C. § 101 be withdrawn.

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<sup>1</sup> The Applicants note that this co-pending patent application has an outstanding Office Action with new rejections under 35 U.S.C. § 101 in connection with new claim amendments.

The Claims are Patentable Over Scholten

Claims 6-12 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 4,969,888 to Scholten et al. (the “Scholten patent”). This rejection is traversed for the reasons below.

Independent claims 6 and 9 each recite “a first region of cancellous bone . . . being compressed” and “a second region of cancellous bone being substantially uncompressed cancellous bone.” The Office Action, however, refers to a state of compressed cancellous bone at one point in time (referencing to col. 7, lines 32-35), and then refers to a state of uncompressed cancellous bone at an earlier point in time (referencing col. 6, lines 47-62). Just because cancellous bone was uncompressed at an earlier point of a medical procedure and then compressed at a later point of the medical procedure, this in no way discloses the presence of both a region of cancellous bone and a region of uncompressed cancellous bone within a given reconstructed vertebral body.

The Applicants respectfully submit that the selection of a component at different points of time, in a non-sequential manner, is improper and that the rejection should be withdrawn. For at least this reason, independent claims 6 and 9, and their dependent claims, are patentable over the Scholten patent. The Applicants respectfully request that the Examiner withdraw the outstanding rejection of claims 6 and 9 under 35 U.S.C. § 102(b).

The Claims are Patentable Over Scholten in view of Kuslich

Claims 6-13 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Scholten patent in view of U.S. Patent 5,571,189 to Kuslich (“the Kuslich patent”). This rejection is traversed for the reasons below.

As discussed above, the Scholten patent fails to anticipate independent claims 6 and 9. The Kuslich patent fails to remedy any deficiencies in Scholten. Thus, the Scholten patent in view of the Kuslich patent fails to disclose or suggest the recitations of independent claims 6 and 9. For at least this reason, claims 6 and 9, and their dependent claims, are patentable over the Scholten patent in view of the Kuslich patent. The Applicants respectfully request that the Examiner withdraw the outstanding rejection of claims 6-13 under 35 U.S.C. § 103(a).

The Claims are Patentable Over Scholten in view of Felt

Claims 6-12 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over the Scholten patent in view of U.S. Patent 6,603,177 to Felt (“the Felt patent”). This rejection is traversed for the reasons below.

As discussed above, the Scholten patent fails to anticipate independent claims 6 and 9. The Felt patent fails to remedy any deficiencies in Scholten. Thus, the Scholten patent in view of the Felt patent fails to disclose or suggest the recitations of independent claims 6 and 9. For at least this reason, claims 6 and 9, and their dependent claims, are patentable over the Scholten patent in view of the Felt patent. The Applicants respectfully request that the Examiner withdraw the outstanding rejection of claims 6-12 under 35 U.S.C. § 103(a).

New Claims 21-32

The new claims 21-23 depend from independent claim 9. These dependent claims are patentable for at least the reasons that they depend from independent claim 9, which are patentable for at least the reasons discussed above.

New independent claim 24 recites “a region of cortical bone,” “a first region of cancellous bone native to the region of cortical bone . . . [and] compressed to define an extravazation-inhibiting barrier,” “a second region of cancellous bone native to the region of cortical bone . . . substantially uncompressed . . . [and] disposed between the region of cortical bone and the first region of cancellous bone,” “a first region of bone filler material defining an extravazation-inhibiting barrier,” “a second region of bone filler material,” and “the first region of bone filler material being disposed between the first region of cancellous bone and the second region of bone filler material.” The cited references fail to disclose these recitations. Thus, independent claim 24 and its dependent claims 25-32 are patentable.

### CONCLUSION

All rejections having been addressed, Applicants respectfully submit that the present application is in condition for allowance, and earnestly solicit a Notice of Allowance, which is believed to be in order. Should the Examiner have any questions regarding this communication, or the application in general, he is invited to telephone the undersigned.


The Director is hereby authorized to charge any appropriate fees under 37 CFR §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 50-1283.

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Respectfully submitted,  
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